United States
Department of
Agriculture

Food Safety
and Inspection
Service

Field
Operations

March 25, 1998

Meat and Poultry Inspection Regulations

Change 98-2

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

CHANGE TRANSMITTAL SHEET

☐ DIRECTIVE
☐ REVISION
☐ AMENDMENT
☒ OTHER

CHANGE 98-2 MEAT AND POULTRY INSPECTION REGULATIONS	98-2	3/25/98

I. PURPOSE

This document transmits changes to Parts 317 and 381 of the MPI Regulations. These changes were published in the Federal Register on February 13, 1998 (63 FR 7279, Docket No. 97-035F), titled Food Labeling: Nutrient Content Claims, Definition of Term; Healthy.

II. CHANGES

SUBCHAPTER A - MANDATORY MEAT INSPECTION

Remove	Insert
Pages 94jjj and 94kkk	Pages 94jjj and 94kkk

SUBCHAPTER C - MANDATORY POULTRY PRODUCTS INSPECTION

Pages 158z(33) and 158z(34)	Pages 158z(33) and 158z(34)

EFFECTIVE DATE: 2/13/98

Deputy Administrator
Office of Policy, Program
Development and Evaluation

Attachment

This covers changes effective as of February 13, 1998.

DISTRIBUTION: M91, M93, M94, M95, CM3, S03, ABB, TRA, PRD, Inspection Offices

OPI: OPPDE

(§ 317.363 continued)

(i) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for "extra lean" in § 317.362.

* (3) The product shall not contain more than 360 mg of sodium, except that it shall not contain more than 480 mg of sodium effective through January 1, 2000, per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 317.309(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that: *

(i) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 480 mg of sodium, * except that it shall not contain more than 600 mg of sodium effective through January 1, 2000, * per labeled serving size; and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 317.309 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh at least 6 oz but less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 317.313(l), and including meal-type products that weigh 10 oz or more per serving (container), shall meet the level for three of the nutrients per labeled serving size.

§§ 317.364 - 317.368 [Reserved]

§ 317.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, expressed or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this Subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of Chapter 1, Title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in Part 56 of Chapter 1, Title 21, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in Part 50 of Chapter 1, Title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in Subchapter D, Title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the

(§ 381.463 continued)

(b)(1) The product shall meet the requirements for "low fat" and "low saturated fat," as defined in § 381.462, except that single-ingredient, raw products may meet the total fat and saturated fat criteria for "extra lean" in § 381.462.

(2) The product shall not contain more than 60 milligrams (mg) of cholesterol per reference amount customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 grams (g) or less or 2 tablespoons (tbsp) or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 ounces (oz) per serving (container), shall not contain more than 90 mg of cholesterol per labeled serving size; and

(ii) Single-ingredient, raw products may meet the cholesterol criterion for "extra lean" in § 381.462.

(3) The product shall not contain more than 360 mg of sodium, except that it shall not contain
* more than 480 mg of sodium effective through January 1, 2000, per reference amount *
customarily consumed, per labeled serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tbsp or less, per 50 g, and, for dehydrated products that must be reconstituted with water or a diluent containing an insignificant amount, as defined in § 381.409(f)(1), of all nutrients, the per-50-g criterion refers to the prepared form, except that:

(i) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh more than 12 oz per serving (container), shall not contain more than 480 mg of sodium,
* except that it shall not contain more than 600 mg of sodium effective through January 1, 2000, *
per labeled serving size; and

(ii) The requirements of this paragraph (b)(3) do not apply to single-ingredient, raw products.

(4) The product shall contain 10 percent or more of the Reference Daily Intake or Daily Reference Value as defined in § 381.409 for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition, except that:

(i) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh at least 6 oz but less than 10 oz per serving (container), shall meet the level for two of the nutrients per labeled serving size; and

(ii) A meal-type product, as defined in § 381.413(l), and including meal-type products that weigh 10 oz or more per serving (container), shall meet the level for three of the nutrients per labeled serving size.

§§ 381.464 - 381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, expressed or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this Subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of Chapter 1, Title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in Part 56 of Chapter 1, Title 21, or was not subject to such requirements in accordance with § 56.104 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in Part 50 of Chapter 1, Title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in Subchapter D, Title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

United States Department of Agriculture
Food Safety and Inspection Service
Room 0157-South Building
Washington, DC
20250

OFFICIAL BUSINESS
Penalty for Private Use, $300

FIRST-CLASS MAIL
POSTAGE & FEES PAID
USDA-FSIS
Permit No. G-42